IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Ryuji UENO

Application No.: 10/567,462 Group Art Unit: 1627
Confirmation No.: 1105 Examiner: Kendra D. Carter
Filed: February 5, 2007

For: COMPOSITION AND METHOD FOR PROMOTING HAIR GROWTH

DECLARATION UNDER RULE 1.132

Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, TABUCHI, Reiko, a citizen of Japan and residing in Kawanishi-shi, Hyogo, Japan declare and say as follows:

1. I graduated from Department of Pharmacy, School of Pharmaceutical Science, Mukogawa Women's University, Hyogo Japan in March 1981 and hold a bachelor's degree in pharmacology.

2. From April 1981 to March 2003, I was an employee of UENO FINE CHEMICALS INDUSTRY, LTD of Osaka, Japan and engaged in the research and development in the field of pharmacology and toxicology. Since April 2003 up to this time, I have been an employee of R-TECH UENO, LTD of Tokyo, Japan.

3. At present, I am a member of The Japanese Society of Toxicology.

4. I am familiar with the subject matter of the above-identified application.

5. I have read the Office Action mailed June 9, 2010 and the references cited therein and am familiar with the

subject matter thereof.

6. In order to show that the invention claimed in the above-identified application is unobvious over Johnstone (US6,262,105) in view of Skuballa et al. (US 4,088,775), the following experiments have been done.

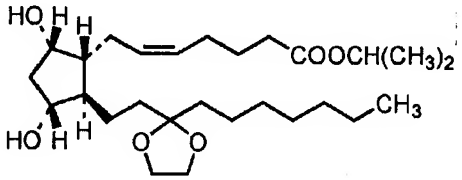
EXPERIMENTS

i. Animals:

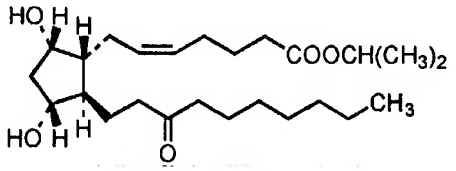
Eight weeks old male C3H/HeN mice were used.

ii. Test substances:

[Test Compound A] 13,14-dihydro-15,15-ethylenedioxy-20-ethyl-PGF2α isopropyl ester



[Test Compound B] 13,14-dihydro-15-keto-20-ethyl PGF2α isopropyl ester (isopropyl unoprostone or Rescula)



Each test compound was dissolved in 70%(w/w) aqueous ethanol. Each dose formulation of test compound was evenly applied topically once daily (100μL per mouse) to the clipped dorsal skin area (approximately 2 x 4 cm) except for Saturday and Sunday for 30 days. The control group received an equal amount of the vehicle in the same manner.

Macroscopic observations of the hair growth were performed 15, 16, 18, 19, 22, 23, 24, 25, 26, 29 and 30 days after the start of the treatment. Hair growth was scored according to the scale below:

− : no hair growth observed

± : hair growth less than 10% of clipped area

+ : hair growth 10-30% of clipped area

++ : hair growth 30-50% of clipped area

+++ : hair growth more than 50% of clipped area

Results are shown in the Table below:

Table: Effects of Topical Application of Compound A and Compound B on Hair Growth in C3H/HeN Mice

Groups	Animal No.	Hair Growth Score Days of Treatments										
		15	16	18	19	22	23	24	25	26	29	30
Control (Vehicle)	11	-	-	-	-	-	-	-	-	-	-	-
	12	-	-	-	-	-	-	-	-	-	-	-
	13	-	-	-	-	-	-	-	-	-	-	-
Compound A (0.005%)	21	-	-	-	-	-	-	-	-	-	±	±
	22	-	-	-	-	-	±	±	±	±	±	±
	23	-	-	-	-	-	-	-	-	-	-	-
Compound A (0.01%)	31	-	-	-	-	-	-	+	+	++	++	++
	32	-	-	-	-	-	-	-	±	±	±	±
	33	-	-	-	-	-	-	-	±	±	±	±
Compound A (0.02%)	41	±	±	±	±	±	+	++	++	+++	+++	+++
	42	±	±	±	±	±	±	+	+	++	++	++
	43	-	±	±	±	±	±	±	±	±	±	±
Compound B (0.005%)	91	-	-	-	-	-	-	-	-	-	-	-
	92	-	-	-	-	-	-	-	-	±	±	±
	93	-	-	-	-	-	-	-	-	-	-	-
Compound B (0.01%)	101	-	-	-	-	-	-	-	-	-	±	±
	102	-	-	-	-	-	-	-	-	±	±	±
	103	-	-	-	-	-	-	-	-	-	-	-
Compound B (0.02%)	111	-	-	-	-	-	±	±	±	±	±	±
	112	-	-	-	-	-	-	-	±	±	±	±
	113	-	-	-	-	-	-	-	-	±	±	±

As shown in the above Table, Compound A, which is the elected species of the instant application, has superior effect on promoting hair growth than isopropyl unoprostone (Compound B) which is a compound disclosed in Johnstone.

7. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Dated this day of Sep. 2, 2010

R. Tabuchi

Reiko TABUCHI